JUL 10 2014

510(k) Summary

510 (K) Number K140626

SPONSOR

Company Name: MeLuna

Company Address: Industriestr 7
Gunzenhausen, GERMANY 91710

Telephone: 210.391.8558

Contact Person: Karin Baker

Summary Preparation Date: July 8, 2014

DEVICE NAME

Trade Name: MeLuna Menstrual Cup (Models Classic and Sport)
Common/Usual Name: Menstrual Cup
Classification Name: Menstrual Cup
Regulation Number: 21 CFR 884.5400
Product Code: HHE
Device Class: Class II

PREDICATE DEVICE

Company	*Product*	*510(k) #*
Diva International, Inc.	Diva Cup	K021356

DEVICE DESCRIPTION

The MeLuna Menstrual Cup is a soft small TPE (Thermoplastic elastomer) menstrual cup that is placed internally in the vagina. The MeLuna is reusable and holds menstrual flow instead of absorbing it. It is available in two size classifications: Standard and Shorty, with cup diameters the same for both Shorty and Regular, but cup capacity and cup length varying between the two classifications.

Capacity		Diameter	Cup Length	
Shorty-	Regular	Shorty/Regular	Shorty	Regular
S - 10ml	S -15 ml	Small – 39 mm	S - 35 mm	S - 46 mm
M - 12ml	M -20ml L	Medium- 42 mm	M- 38 mm	M - 50mm
- 15ml	L - 24 ml XL	Large - 45 mm	L - 41 mm	L - 53mm
- 18ml	XL - 30 ml	X Large - 48 mm	XL - 43 mm	XL - 57mm

The cups are available in two different firmness levels referred to as Classic or Sport. The Classic material has a shore rating of 40; the firmer Sport model has a shore rating of 50.

INDICATIONS FOR USE

The MeLuna Menstrual Cup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

COMPARISON OF PREDICATE PRODUCT TECHNICAL CHARACTERISTICS

The MeLuna Menstrual Cup is similar to the predicate device in indications for use, operating principle, and device design. The MeLuna differs from the predicate device in material, and in slight differences in dimensions and capacity. These differences do not raise new types of safety or effectiveness questions.

NON-CLINICAL PERFORMANCE DATA

BIOCOMPATIBILITY

The MeLuna Menstrual Cup was tested in accordance with the testing requirements of ISO-10993-1:2009 (R2013), "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for cytotoxicity, sensitization, irritation, and acute systemic toxicity testing. In addition, a use-life testing supported a three-years use-life, and cleaning/disinfection validation testing demonstrated acceptability of cleaning and disinfection procedures included in the Instructions for Use.

CONCLUSION

The MeLuna Menstrual Cup is similar to the predicate products in indications for use, operating principle, and device design. The differences in material, dimensions and capacity do not introduce new issues in terms of safety and efficacy, and MeLuna concludes that the MeLuna Menstrual Cup is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 10, 2014

Meluna
% Yolanda Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K140626
Trade/Device Name: MeLuna Menstrual Cup (Models Classic and Sport)
Regulation Number: 21 CFR§ 884.5400
Regulation Name: Menstrual Cup
Regulatory Class: Class II
Product Code: HHE
Dated: June 3, 2014
Received: June 5, 2014

Dear Yolanda Smith,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301)796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140626

Device Name
MeLuna Menstrual Cup (Models Classic and Sport)

Indications for Use *(Describe)*

The MeLuna Menstrual Cup is a receptacle placed in the vagina to collect blood and cellular debris that is extruded from the uterus via the cervix during menstruation.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Glenn B. Bell -S for BRF

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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